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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE KENVUE INC. SECURITIES LITIGATION This Document Relates To: ALL CASES	Master File No. 3-23-cv-20998-ZNQ-JBD

DEFENDANTS' BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes, Regulations & Other Authorities

Kenvue Inc., the Individual Defendants, Johnson & Johnson, and the Underwriter Defendants submit this brief in support of their motion to dismiss Plaintiffs' consolidated amended complaint (the "Complaint" or "AC"), ECF 38.

PRELIMINARY STATEMENT

Kenvue is the world's largest pure-play consumer health company by revenue. It had $15.4 billion in net sales in 2023 across 85 iconic brands, including Tylenol, Johnson's Baby, Band-Aid, Neosporin, Neutrogena, Listerine, Aveeno, Benadryl, Zyrtec, Motrin, Nicorette, and Lubriderm. Kenvue was incorporated in 2022 in connection with J&J's separation of its consumer health business, and became a standalone public company via an IPO in May 2023.

This litigation is the predictable result of Kenvue going public in an environment where IPOs and stock price declines are routinely followed by opportunistic securities claims. In September 2023, Kenvue's stock declined $1.01; a few weeks later this case was filed. Plaintiffs allege that the 1,525 pages of final registration statements and prospectuses from Kenvue's May 2023 IPO and August 2023 "Exchange Offer" should have included a description of a public FDA proceeding about a citizen petition that had been pending since 2015. There is no duty to repeat such public information in registration statements and prospectuses. Plaintiffs' claims should be dismissed with prejudice.

The FDA proceeding at issue concerns a citizen petition submitted in 2015. That petition, like one submitted by the same parties in 2007, contended that phenylephrine (often referred to as "PE") was not effective at relieving nasal congestion in certain (though not all) formulations. PE is an over-the-counter ingredient used in products that make up about 2% of Kenvue's global revenue.

The Complaint does not allege that any information about the FDA proceeding or about PE was concealed from investors. Nor does it claim that any Defendant acted in bad faith. Plaintiffs argue only that already-public information related to the FDA proceeding should have been included in the May and August 2023 offering materials. The omission, they say, led investors to underestimate the risk that, in September 2023, an advisory body called the Non-prescription Drugs Advisory Committee (the "NDAC") would make a non-binding recommendation to the FDA that oral PE is not effective at current dosages.

To be clear: There is no safety issue. There have been no recalls. There is no FDA enforcement proceeding. The regulatory review of PE was not begun by the FDA. The FDA has, by regulation, classified PE as "Generally Recognized as Safe and Effective" for 30 years. And as of the filing of this motion in May 2024 – a full year after Kenvue's IPO – the FDA has *still* not taken any regulatory action to change PE's status based on the NDAC's non-binding recommendation.

This is not the stuff of securities litigation. Nor should it be. Kenvue is a global, diversified company with hundreds of products and thousands of ingredients. It was already well-known to investors and the market from its history of SEC reporting as J&J's consumer health business. Indeed, the class Plaintiffs seek to represent would overwhelmingly be comprised of former J&J shareholders who chose to exchange their J&J shares for Kenvue shares in the Exchange Offer. Requiring Kenvue to expand its already-lengthy SEC filings to repeat already-public information about individual ingredients, and to speculate about what an advisory body might do regarding an 8-year-old citizen petition, would bury investors in trivial information and undermine informed decision-making. The Supreme Court and the Third Circuit have warned against such a result.

None of Kenvue's statements were factually inaccurate or misleading. None omitted information required to be disclosed, and no relevant information was unavailable to investors. Kenvue provided extensive cautionary language regarding regulatory risks, including specifically warning that the FDA regulated its ingredients, and that regulatory determinations regarding ingredients' efficacy could have adverse impacts on Kenvue. That is all the securities laws require.

The Complaint should be dismissed with prejudice.

BACKGROUND

A. 1976 Through March 2023: Public FDA Regulatory Proceedings And Scientific Debate About PE's Efficacy.

The FDA began studying PE as an OTC nasal decongestant in 1976. AC ¶ 84. After 18 years of study, the FDA made a regulatory determination in 1994 that PE is safe and effective for OTC use, classifying PE as "Generally Recognized as Safe and Effective" ("GRASE"). *Id.* Products containing ingredients that are GRASE do not require preapproval by the FDA before they are marketed. *Id.* ¶ 81.

The FDA's classification of PE as GRASE was challenged in February 2007 by a "citizen petition." *Id.* ¶ 86. Federal regulations allow individuals to submit petitions to the FDA seeking regulatory action, and provide for an administrative proceeding regarding the petition. 21 C.F.R. § 10.30(b)(3). The 2007 petition was submitted by 3 professors. AC ¶ 86. It did not challenge PE's safety; it questioned only PE's efficacy in relieving congestion. *Id.* In December 2007, the NDAC, an advisory body that makes non-binding recommendations to the FDA, voted that the "available evidence 'is suggestive of efficacy.'" *Id.* ¶ 87 & n.11.

In November 2015, 2 of the same professors submitted a second citizen petition challenging PE's efficacy. *Id.* ¶ 88. The 2015 petition argued that new studies suggested a lack of efficacy for oral (though not nasal) PE, and that these studies outweighed the prior ones that had demonstrated efficacy. *See id.* Over the course of the next 8 years, the efficacy of PE continued to be studied and debated

in scientific journals and conferences, and through the FDA's administrative proceeding. The proceeding was, of course, public. In particular: comments for and against the 2015 petition were filed on the FDA's public docket for the petition; the professors publicly filed a supplement to their petition in May 2022; and further comments for and against the petition were filed on the public docket. *See id.* ¶¶ 90-92; Ex. G-2 (2015 citizen petition docket).[1]

On March 3, 2023, the FDA announced that the NDAC would meet on April 12, 2023, to consider a non-binding recommendation regarding the 2015 citizen petition. AC ¶¶ 87 n.11, 93. On March 21, 2023, the FDA postponed the NDAC meeting. *Id.* ¶ 94. On July 12, 2023, the NDAC meeting was rescheduled for September 11-12, 2023. *Id.* ¶ 96; Ex. G-3 (NDAC meeting docket).[2]

B. May 2023: The IPO.

On May 4, 2023, Kenvue shares began publicly trading on the New York Stock Exchange. *Id.* ¶ 72. Kenvue's IPO was the culmination of a years-long process. In 2021, J&J had announced plans to separate its consumer health business into a standalone public company. *Id.* ¶ 65. Over the course of 2022 and early 2023, the Kenvue name was announced, as were its directors and officers.

[1] *See* www.regulations.gov/docket/FDA-2015-P-4131/document; www.regulations.gov/docket/FDA-2015-P-4131/comments.
[2] The FDA opened a new docket in July 2023 for the September 2023 NDAC meeting. *See* www.regulations.gov/document/FDA-2023-N-2653-0001.

See id. ¶¶ 66-67. Several drafts of the registration statement were publicly filed with the SEC from January to May 2023. *Id.* ¶¶ 70-71. The registration statement and the prospectus became effective on May 3 and 4, 2023, respectively. *See id.*

The final IPO registration statement was 454 pages, Ex. C; the final IPO prospectus was 316 pages, Ex. D.[3] Both documents (together, the "IPO Registration Statement") contained extensive cautionary language regarding regulatory risks in and outside of the US, including regarding ingredients. For example, they stated the following regarding FDA regulatory risks:

- Kenvue is "subject to extensive government regulations in the United States and around the world. U.S. federal authorities, including the [FDA], the [FTC], the [CPSC], the [OSHA], the [EPA] and the [DEA], regulate various aspects of our business, along with parallel authorities at the state and local levels and comparable authorities in other jurisdictions. Government regulations in the United States and around the world apply to many areas of our business, including most aspects of our products. . . . In addition, the global regulatory landscape is subject to rapid and unexpected changes, . . . and there has been a general trend toward increasingly stringent regulation and enforcement around the world in recent years." Ex. C at 157.
- "Compliance with or enforcement actions related to these laws and regulations could adversely affect our business, results of operations or financial condition." *Id.* at 43.
- "The FDA may determine that [a certain type of] notification does not provide an adequate basis to conclude that a new ingredient is reasonably expected to be safe, which could effectively prevent the marketing of the ingredient." *Id.* at 161.

[3] Defendants' exhibits are integral to or explicitly relied on in the Complaint, are publicly available, and may be considered on this motion to dismiss. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

- "[T]he FDA and comparable authorities in other jurisdictions regulate the facilities and operational procedures that we use to manufacture our products. . . . Failure to comply with cGMP [current Good Manufacturing Practices] or similar manufacturing standards at one of our or our third-party partners' facilities could result in adverse regulatory action." *Id.* at 43.

- "Most of our OTC products marketed in the United States, . . . are regulated pursuant to the FDA's monograph system. The monographs establish the conditions, such as active ingredients, uses (indications), doses, labeling and testing, under which an OTC drug is generally recognized as safe and effective and can be marketed without an NDA and FDA premarket approval." *Id.* at 158-59.

- "The Over-the-Counter Monograph Safety, Innovation, and Reform Act, enacted in March 2020, is expected to introduce significant reform to the OTC monograph system, including by replacing the FDA's existing rulemaking process with an administrative order process for issuing, revising and amending OTC monographs." *Id.* at 159.

- "New or more stringent laws or regulations, more restrictive interpretations of existing laws or regulations or increased enforcement actions by governmental and regulatory agencies around the world could increase our ongoing costs of compliance, alter the environment in which we do business or otherwise adversely affect our business, results of operations or financial condition." *Id.* at 157.

- "In the event that the FDA determines that one of our products fails to comply with FDA regulations, we may be required, or we may independently decide, to conduct a recall or market withdrawal of that product or to correct the failure by making changes to that product, including its manufacturing, formulation or label." *Id.* at 160.

See also id. at 26-74 ("Risk Factors" section), 75-77 (forward-looking statements cautionary notes), 157-65 ("Government Regulations" section).

J&J, through the Underwriter Defendants, sold approximately 199 million Kenvue shares in the IPO. AC ¶ 73. This was about 10% of Kenvue's shares. *Id.*

C. August 2023: The Exchange Offer.

In July 2023, J&J announced that it had received a waiver of its lock-up agreement, and that it would distribute most of its Kenvue shares to current J&J shareholders through an "Exchange Offer." *Id.* ¶ 75. J&J shareholders had the option of tendering their J&J shares to J&J in exchange for Kenvue shares owned by J&J, at a 7% discount (subject to certain limits). *See id.*

Several drafts of the registration statement for the Exchange Offer were publicly filed with the SEC from July to August 2023. *Id.* ¶ 76. The registration statement and prospectus became effective on August 14, 2023. *Id.*

The final Exchange Offer registration statement was 383 pages, Ex. E; the final Exchange Offer prospectus was 372 pages, Ex. F. Both documents (together, the "Exchange Offer Registration Statement") contained substantially similar cautionary language regarding regulatory risks as the IPO Registration Statement. *See, e.g.,* Ex. E at 27-77 ("Risk Factors" section), 78-79 (forward-looking statements cautionary notes), 183-91 ("Government Regulations" section).

The Exchange Offer expired on August 18, 2023, and J&J exchanged roughly 191 million J&J shares for 1.5 billion Kenvue shares. AC ¶ 77. J&J retained about 10% of Kenvue's shares. *Id.* ¶ 79.

D. September 2023: The NDAC's Non-Binding Recommendation Regarding The 2015 Citizen Petition.

On September 11 and 12, 2023 – 4 months after the IPO and a month after the Exchange Offer – the NDAC met to discuss PE. *Id.* ¶ 99. The meeting was an "open public hearing" and was webcast live.[4] Prior notice of the meeting was posted on the FDA's website and in the Federal Register. *See* 21 C.F.R. § 14.20(a).

The NDAC meeting included presentations by a number of individuals and groups with different perspectives on the efficacy of PE and on the studies under consideration.[5] *See, e.g.,* AC ¶ 12 (noting the "dueling briefs and presentations" at the meeting). For example, Howard M. Druce, MD, Clinical Professor of Medicine at Rutgers New Jersey Medical School, presented his opinion that the body of clinical evidence supported PE's efficacy. Ex. I at 170-89 (NDAC meeting transcript excerpt).[6] He discussed multiple studies, including "a large randomized, double-blind, placebo-controlled study to evaluate the effectiveness of phenylephrine . . . for the common cold." *Id.* at 175. He concluded:

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[4] *See* www.fda.gov/advisory-committees/advisory-committee-calendar/updated-september-11-12-2023-meeting-nonprescription-drugs-advisory-committee-meeting-announcement (notice); www.fda.gov/media/171914/download (webcast recording).
[5] The full meeting materials, including the minutes, agenda, briefings, and transcript, are on the FDA's website: www.fda.gov/advisory-committees/advisory-committee-calendar/updated-september-11-12-2023-meeting-nonprescription-drugs-advisory-committee-meeting-announcement#event-materials.
[6] *See* www.fda.gov/media/173340/download. Dr. Druce's address was part of the presentation facilitated by the Consumer Healthcare Products Association.

> In summary, oral phenylephrine 10 milligrams provides temporary relief of congestion due to the common cold and upper respiratory allergies, which is the labeled indication. There is ample clinical evidence, based mostly on the common cold model, to justify the labeled indication, with FDA determining regulatory status as GRAS/GRAE based on what I consider an appropriate clinical endpoint. The monographed studies are methodologically sound and are still relevant to support GRAS/GRAE status. No compelling data have been presented to date to challenge this existing efficacy data.

Id. at 188. Further information for and against PE's efficacy was presented during the 2-day meeting. *See generally id.*

The NDAC voted to recommend to the FDA that "current scientific data that were presented" does not "support that the monographed dosage of orally administered [PE] is effective." AC ¶ 107. The NDAC did not conclude that other dosages or forms of PE, such as nasal sprays, were not effective. *See id.*

E. The Complaint.

Like many IPOs, Kenvue's quickly became the target of litigation. This case was filed in October 2023. ECF 1. Joseph Ditta was appointed as Lead Plaintiff in December 2023. ECF 32. Ditta and new Plaintiff David Gruthoff filed the operative amended complaint in March 2024. ECF 38.

The Complaint names 34 Defendants: Kenvue, 3 Kenvue "Officer Defendants," 10 Kenvue "Director Defendants," J&J, and 19 "Underwriter Defendants." AC ¶¶ 22-63. It asserts claims under Section 11, Section 12(a)(2), and Section 15 of the Securities Act of 1933. For the IPO, the Section 11 and Section 12(a)(2) claims are asserted against Kenvue, the Officer Defendants, and

the Underwriter Defendants; the Section 15 claims are asserted against the Officer Defendants and J&J. *Id.* Counts I-III. For the Exchange Offer, the Section 11 and Section 12(a)(2) claims are asserted against Kenvue, the "Individual Defendants" (i.e., both the Officer and the Director Defendants), and J&J; the Section 15 claims are asserted against the Individual Defendants and J&J. *Id.* Counts IV-VI.[7]

The Section 11 and Section 12(a)(2) claims allege that three statements made in both the IPO Registration Statement and the Exchange Offer Registration Statement were "materially false and/or misleading." *Id.* ¶¶ 153, 166, 181, 194.[8] The "Risk Factor Statement" concerned risk factors for Kenvue's business; the "Tylenol Studies Statement" concerned studies about Tylenol products; and the "OTC Monograph Statement" concerned the FDA's OTC monograph system applicable to certain of Kenvue's products. *Id.* ¶¶ 123-43.

The following table shows the challenged text from each statement:[9]

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[7] Although the Underwriter Defendants did not act as underwriters for the Exchange Offer and none are listed as Defendants in the headings for Counts IV and V, there are references to them in the body of those Counts. Those references appear to be errors, and Defendants assume the Underwriter Defendants are not Defendants for those Counts. *Cf.* AC ¶¶ 41-59 (alleging they only acted as underwriters for the IPO). If Plaintiffs are asserting those claims against the Underwriter Defendants, they fail for the same reasons as for the other Defendants.

[8] The IPO Registration Statement refers to Kenvue using "we" and "our," whereas the Exchange Offer Registration Statement refers to "Kenvue" and "Kenvue's." *Compare, e.g.,* AC ¶ 126 *with* ¶ 136. Otherwise, the statements are identical.

[9] Following standard practice in securities litigation, the Complaint bolds and italicizes the specific text alleged to be misleading. This emphasis is not repeated here. *See also* Ex. A (table of challenged statements with Complaint's emphasis).

Statement	Challenged Text
Risk Factor Statement ¶¶ 126, 136	"Concerns about the reliability, safety or efficacy of our products or their ingredients, whether raised internally or by litigants, regulators, consumer advocacy groups, third-party interest groups or others, and whether or not based on scientific or factual evidence, have resulted, and could in the future result, in governmental investigations, regulatory action (including the shutdown of manufacturing facilities), private claims and lawsuits, significant remediation and related costs, safety alerts, product shortages, declining sales or reputational damage (including damage to brand image, brand equity and consumer trust in our products). . . . [W]e believe our products are reliable, safe and effective when used for their intended purposes in accordance with label directions."
Tylenol Studies Statement ¶¶ 128, 138	"Studies sponsored by Johnson & Johnson Consumer Inc. and by third parties have shown that these [Tylenol] products help relieve, among other things, headache and muscle pain, arthritis pain, sinus and nasal congestion, fever and pain with sleeplessness."
OTC Monograph Statement ¶¶ 130, 140	"Products marketed under the OTC monograph system are required to conform to specific quality, formula and labeling requirements. OTC monograph products that do not comply with these standards can be deemed unapproved new drugs and can be required to be withdrawn from the market. The Over-the-Counter Monograph Safety, Innovation, and Reform Act, enacted in March 2020, is expected to introduce significant reform to the OTC monograph system, including by replacing the FDA's existing rulemaking process with an administrative order process or issuing, revising and amending OTC monographs."

Plaintiffs do not allege that anything in these three challenged statements was affirmatively false. Rather, the Complaint alleges that these statements were misleading because they "failed to disclose" certain "adverse facts" about PE. *Id.* ¶¶ 127, 129, 131, 137, 139, 141. Specifically, the Complaint alleges that the

following "adverse facts" should have been included in the IPO Registration Statement and the Exchange Offer Registration Statement:

- "Substantial concerns had been raised about the effectiveness of products containing PE for more than a decade, and those concerns proved to be well-founded." *Id.* ¶¶ 127(a), 129(a), 131(a), 137(a), 139(a), 141(a).
- Five studies and clinical trials from 2009 to 2018 – Horak 2009, Day 2009, Meltzer 2015, Meltzer 2016, and JJCI 2017-2018 – had "demonstrated that oral PE is ineffective." *Id.* ¶¶ 127(b), 129(b), 131(b), 137(b), 139(b), 141(b).
- "In November 2015, two University of Florida professors submitted a citizen petition to the FDA asking the FDA to issue a final rule removing oral PE" as GRASE. *Id.* ¶¶ 127(c), 129(c), 131(c), 137(c), 139(c), 141(c).
- In 2022, the professors "submitted a supplement to their November 2015 citizen petition," "the American College of Clinical Pharmacy submitted a comment to the FDA in support of the November 2015 citizen petition," and "the American Association of Colleges of Pharmacy submitted a comment in support of the November 2015 citizen petition." *Id.* ¶¶ 127(d)-(f), 129(d)-(f), 131(d)-(f), 137(d)-(f), 139(d)-(f), 141(d)-(f).
- On "March 3, 2023, the FDA announced a meeting of the NDAC for April 12, 2023 to discuss the adequacy of efficacy data available for oral phenylephrine," and then postponed the meeting on March 21, 2023. *Id.* ¶¶ 127(g)-(h), 129(g)-(h), 131(g)-(h), 137(g)-(h), 139(g)-(h), 141(g)-(h).
- The NDAC's "forthcoming meeting . . . on the efficacy of oral PE" was to be "one of the first test cases for the March 2020 law that overhauled the monograph system." *Id.* ¶¶ 131(i), 141(j).
- "On July 12, 2023, the FDA announced that" the NDAC meeting "was to be held on September 11 and 12, 2023." *Id.* ¶¶ 137(i), 139(i), 141(i) (only for the Exchange Offer Registration Statement).

Plaintiffs effectively concede that these "adverse facts" were publicly available before the relevant Registration Statement. *See, e.g., id.* ¶¶ 89-90 (describing "public" comments submitted to the FDA), 96 (noting the "public

advisory meeting of the NDAC" and the FDA's "public" docket for that meeting). They also admit that "the investing and general public were largely familiar" with Kenvue and its products from the long history of public disclosures when it was J&J's consumer health business. *See id.* ¶ 69.

The Complaint nonetheless claims the IPO and Exchange Offer Registration Statements were required by the federal securities laws to repeat this already-public information. It alleges that the "adverse facts" relating to the citizen petition and the NDAC meeting made "regulatory action by the FDA" "probable and imminent," and "the failure to disclose the pendency of these proceedings and the underlying studies demonstrating the ineffectiveness of oral PE caused investors to materially underestimate the risk" "that there would be a determination that oral PE was not effective." *Id.* ¶ 127(j). "Plaintiffs do not claim that any of the defendants . . . engaged in intentional or reckless misconduct or acted with fraudulent intent." *Id.* ¶ 152.

The Complaint alleges that Plaintiffs and putative class members were damaged because Kenvue's share price declined $1.01 on September 12, 2023, based "[o]n the news" late that afternoon of the NDAC's non-binding recommendation. *Id.* ¶ 15. The Complaint omits the publicly disclosed fact that

sales of products containing PE represent "just 2% of [Kenvue's] global revenue." Ex. J at 7 (earnings call transcript excerpt).[10]

LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the "Complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (cleaned up). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

To state a Section 11 claim, the Complaint must plead that a registration statement contained "an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). To state a Section 12(a)(2) claim, the Complaint must plead that a prospectus contained "an untrue statement of a material fact or omit[ted] a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading." 15 U.S.C. § 77*l*(a)(2). "The analysis of claims made pursuant to Section 11 and Section 12(a)(2) is essentially the same," *N.J. Carpenters Vacation Fund v. RBS Grp., PLC*, 720 F. Supp. 2d 254, 268 (S.D.N.Y. 2010). In particular, any challenged statement is evaluated from the perspective of a "a reasonable person

[10] *See* investors.kenvue.com; *see also* AC ¶ 116 (discussing this earnings release).

reading the statement fairly and in context." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pens. Fund*, 575 U.S. 175, 194 (2015).

To state a Section 15 control-person claim, the Complaint must plead "(1) a primary violation of the federal securities laws by a controlled person or entity; (2) control of the primary violator by the defendant; and (3) that the controlling person was in some meaningful way a culpable participant in the primary violation." *Carmack v. Amaya Inc.*, 258 F. Supp. 3d 454, 466 (D.N.J. 2017) (cleaned up).

ARGUMENT

I. The Complaint Fails To State Section 11 Or Section 12(a)(2) Claims.

The Section 11 and Section 12(a)(2) claims should be dismissed because: (1) the challenged statements were not misleading; (2) there was no duty to disclose the allegedly omitted facts; (3) Kenvue's opinion statements are not actionable; and (4) Kenvue was not required to predict the NDAC's vote.

A. The Challenged Statements Were Not Misleading.

Plaintiffs do not – and could not – allege that any of the 3 challenged statements are inaccurate, i.e., contain untrue statements of material fact. The Complaint alleges only that the Risk Factor Statement, the Tylenol Studies Statement, and the OTC Monograph Statement each "failed to disclose" certain "adverse facts" about PE. *See* AC ¶¶ 127, 129, 131, 137, 139, 141. But this purported omission did not create any misleading impression about PE or the risks to Kenvue from the NDAC's review of PE's efficacy.

Risk Factor Statement. Each of the IPO and Exchange Offer Registration Statements contain detailed 50-page sections on "Risk Factors." *See, e.g.,* Ex. C at 26-74. The Complaint singles out one statement concerning regulatory risks relating to Kenvue's products and ingredients. AC ¶¶ 126, 136. In the statement, Kenvue warned investors of the specific type of risk at issue here:

> Concerns about the reliability, safety or efficacy of our products or their ingredients, whether raised internally or by litigants, regulators, consumer advocacy groups, third-party interest groups or others, and whether or not based on scientific or factual evidence, have resulted, and could in the future result, in governmental investigations, regulatory action . . . and lawsuits, . . . [even though] we believe our products are reliable, safe and effective.

E.g., Ex. C at 45-46.

A "statement is misleading if a reasonable investor would have received a false impression from the statement." *In re Facebook, Inc. IPO Sec. & Deriv. Litig.*, 986 F. Supp. 2d 487, 517 (S.D.N.Y. 2013). The Complaint does not explain how a reasonable investor, reading the Risk Factor Statement fairly and in context, would have come away with any false impression about the risk regarding PE.

Plaintiffs do not deny that reasonable investors were aware that Kenvue was subject to regulatory risk in connection with the efficacy of its ingredients. Nor do they deny that Kenvue genuinely believed – and still believes – that its products and ingredients, including PE, are effective. Instead, they assert only that the Risk Factor Statement "caused investors to materially underestimate the risks that Kenvue faced with respect to its products containing PE" as a result of possible

future "regulatory action by the FDA and its NDAC panel." AC ¶¶ 127(j), 137(k). But as the Complaint concedes, the Risk Factor Statement "made no mention of phenylephrine (or PE) by name." *Id.* ¶ 128. This is fatal: Defendants did not downplay – or characterize at all – the possible future regulatory risk regarding PE, so they caused no false impression about it.

Plaintiffs' case thus boils down to a claim that they think it would have been helpful for certain "facts" to have been included in the Registration Statements. That is not sufficient to state a claim under the federal securities laws. "There is no affirmative duty to disclose any and all material information." *Turnofsky v. electroCore, Inc.*, 2023 WL 4527553, at *7 (D.N.J. July 13, 2023) (Quraishi, J.) (cleaned up); *In re Adams Golf, Inc. Sec. Litig.*, 381 F.3d 267, 277 (3d Cir. 2004) (same); *Wandel v. Gao*, 590 F. Supp. 3d 630, 640 (S.D.N.Y. 2022) ("[A] corporation is not required to disclose a fact merely because a reasonable investor would very much like to know that fact."). Because the Risk Factor Statement did not create any false impression about the risk of regulatory action regarding PE, Defendants had no obligation to include the information Plaintiffs allege was omitted. *See In re Amarin Corp. PLC Sec. Litig.*, 2022 WL 2128560, at *3 (3d Cir. 2022) (Section 10(b) case: because statements "did not make any affirmative characterizations regarding the effectiveness of" a product, they were not misleading and did not "put into play" the allegedly omitted information); *In re*

Cognizant Tech. Sols. Corp. Sec. Litig., 2018 WL 3772675, at *21 (D.N.J. Aug. 8, 2018) (similar).[11]

Tylenol Studies Statement. Plaintiffs' claims about this statement suffer from the same flaw. The challenged portion said: "Studies sponsored by Johnson & Johnson Consumer Inc. and by third parties have shown that these [Tylenol] products help relieve, among other things, headache and muscle pain, arthritis pain, sinus and nasal congestion, fever and pain with sleeplessness." AC ¶¶ 128, 138.

This is true. Plaintiffs do not contend otherwise; they claim only that *other* studies show that the *ingredient* PE is not effective at relieving congestion. *Id.* ¶¶ 129(b), 139(b). But as the Complaint acknowledges, this statement, too, "made no mention of phenylephrine (or PE)"; it was "about Kenvue's full line of Tylenol *products*."[12] *Id.* ¶ 128 (emphasis added). Just like the Risk Factor Statement, no reasonable investor would have read the Tylenol Studies Statement as falsely reassuring them about the risk of regulatory action regarding the efficacy of a single ingredient, PE. *See, e.g., Turnofsky*, 2023 WL 4527553, at *7.

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[11] The Third Circuit uses the same analysis to evaluate whether an omission renders a statement misleading under Section 11, Section 12(a)(2), and Section 10(b) of the federal securities laws. *E.g., In re Craftmatic Sec. Litig.*, 890 F.2d 628, 641 (3d Cir. 1989); *see also Rombach v. Chang*, 355 F.3d 164, 178 n.11 (2d Cir. 2004) ("The test for whether a statement is materially misleading under Section 12(a)(2) is identical to that under Section 10(b) and Section 11."); *In re Pretium Res. Inc. Sec. Litig.*, 256 F. Supp. 3d 459, 472 n.7 (S.D.N.Y. 2017) (same).

[12] The Complaint ignores Tylenol products with pseudoephedrine (*not* PE), though Plaintiffs do not contest that pseudoephedrine is effective in relieving congestion.

This is confirmed by the statement's context. It was part of a section labeled "Our Brands and Product Portfolio." *E.g.,* Ex. C at 134-40. That section provided a high-level overview of Kenvue's "world-class portfolio of iconic, trusted brands" with 1-paragraph highlights of 22 different "key brands." *Id*. (highlighting these brands by logo); *see also id.* at 135 (Tylenol overview). The Tylenol Studies Statement cannot be read, fairly and in context, to characterize *all* studies relating to Tylenol products or ingredients, let alone to suggest that there were no contrary studies concerning one particular (unnamed) ingredient, PE.

Claims like Plaintiffs' are regularly dismissed because courts recognize that companies do not have to comprehensively canvas the scientific literature any time they talk about a positive scientific study. *See, e.g., In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012) (Section 10(b) case: statement not misleading because "a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant"); *In re Philip Morris Int'l Inc. Sec. Litig.*, 2021 WL 4135059, at *11 (S.D.N.Y. Sept. 10, 2021) (Section 10(b) case: statement not misleading because no investor "would have interpreted the reporting of clinical results as necessarily implying the release of all available, non-clinical, data on the subject"); *Huang v. Avalanche Biotech. Inc.*, 2016 WL 6524401, at *6-9 (N.D. Cal. Nov. 3, 2016) (Section 10(b)

and Section 11 case: "reasonable investors would not be misled" where defendants "never claimed that the safety data [they reported] was all the safety results").

OTC Monograph Statement. Plaintiffs' theory is especially weak here. The challenged statement was included in the section titled "Government Regulations," which provided a broad overview of the legal framework under which Kenvue operates. *See, e.g.*, Ex. C at 157-65. PE is not mentioned anywhere in this section. The statement merely explains that OTC products are generally regulated under the FDA's OTC monograph system, and that the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2020 had reformed that system. AC ¶¶ 130, 140.

The OTC Monograph Statement is accurate, as the Complaint implicitly acknowledges. *See id.* ¶¶ 131, 141. It does not mention any particular ingredient, product, or FDA proceeding. The suggestion that any reasonable investor would have read this general statement about the OTC regulatory framework and come away with a false impression about PE or the NDAC is nonsensical. Considering "the full context, Plaintiff[s] ha[ve] not pled how Defendants' statements would have misled a reasonable investor," *Spar v. Celsion Corp.*, 2023 WL 2069725, at *6-7 (D.N.J. Feb. 6, 2023) (Quraishi, J.) (Section 10(b) case).

B. There Was No Duty To Disclose The Allegedly Omitted Facts.

Plaintiffs' Section 11 and Section 12(a)(2) claims also fail because the IPO and Exchange Offer Registration Statements did not have to include the "adverse

facts" about PE identified in the Complaint. As discussed above, the allegedly omitted facts were not necessary to avoid any challenged statement from being misleading about PE. The allegedly omitted information also was not required to be in the Registration Statements because the information was already publicly available and thus not material, and it was not required by Item 105.

Every Allegedly Omitted Fact About PE Was Publicly Available And Thus Not Material. The Complaint alleges that the challenged statements "failed to disclose" the following:

- In November 2015, 2 professors submitted to the FDA a citizen petition contending that oral PE was ineffective.
- In 2022, the professors submitted to the FDA a supplement to their petition.
- Comments supporting the 2015 citizen petition were submitted to the FDA by the American College of Clinical Pharmacy and the American Association of Colleges of Pharmacy.
- The 2015 citizen petition and 2022 supplement cited 5 studies from 2009 to 2018 that had addressed oral PE's efficacy.
- The FDA announced an NDAC meeting about oral PE's efficacy for April 2023, then postponed that meeting, then scheduled it for September 2023.
- The review of oral PE's efficacy was one of the first proceedings decided after recent changes to the FDA's monograph system.

See AC ¶¶ 127, 129, 131, 137, 139, 141.

Every one of these facts was public. Federal regulations require FDA proceedings, including citizen petitions, related comments, and NDAC meetings, to be available and open to the public. *E.g.,* 21 C.F.R. §§ 10.20(j)(1), 14.20,

14.22(b, e), 14.5. Every citizen petition and comment Plaintiffs cite was accessible on the FDA's website and the Federal Government's official Regulation.gov website. *See* Ex. G (screenshots of public FDA dockets). And all of the studies cited by Plaintiff were described at length in the public FDA filings, on the Federal Government's official ClinicalTrials.gov website, as well as available in medical journals. *See* Ex. B (table showing where all allegedly omitted information was publicly available); *see also* Ex. H (medical journal publications).[13] Nothing was concealed from investors.

This defeats Plaintiffs' case entirely. A fact is material if there is "a substantial likelihood that [disclosure] would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 377 (3d Cir. 1993) (cleaned up). The Third Circuit has long held that already-public information is not material because its repetition in SEC filings like the Registration Statements would not

[13] The 2015 citizen petition and supplement describe studies cited by Plaintiffs in detail. *See* www.regulations.gov/docket/FDA-2015-P-4131/document. The comments by the American College of Clinical Pharmacy and the American Association of Colleges of Pharmacy are available here: www.regulations.gov/document/FDA-2015-P-4131-0001/comment. The FDA's 89-page, detailed briefing document containing links to further materials and citing more than 30 studies is available here: www.fda.gov/media/171915/download. The FDA's website for the NDAC's review is available here: www.fda.gov/advisory-committees/advisory-committee-calendar/updated-september-11-12-2023-meeting-nonprescription-drugs-advisory-committee-meeting-announcement.

change the total mix of information available to reasonable investors. *See, e.g., Klein v. Gen. Nutrition Cos., Inc.*, 186 F.3d 338, 343 (3d Cir. 1999) (rejecting Section 11 claim where omitted information was not "private, internal [company] information," because the "[f]ederal securities laws do not require a company to state . . . public knowledge"); *Trump*, 7 F.3d at 377 (rejecting claim that prospectus omitted information that was publicly known because "the inclusion of this information would not have substantively altered the total mix of information").

Indeed, this proposition is one of the more well-established in securities litigation. *See, e.g., Wielgos v. Commonwealth Edison Co.*, 892 F.2d 509, 517 (7th Cir. 1989) ("It is pointless and costly to compel firms to reprint information already in the public domain."); *Seibert v. Sperry Rand Corp.*, 586 F.2d 949, 952 (2d Cir. 1978) (Section 14 case: "reasonable minds could not differ as to the immateriality of the omissions" of "information already in the public domain"); *Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1162-63 (9th Cir. 2009) (citing *Klein*, *Wielgos*, and *Seibert*: "As many of our sister circuits have recognized, it is pointless and costly to compel firms to reprint information already in the public domain. Section 11 does not require the disclosure of all information a potential investor might take into account when making his decision") (cleaned up); *Kapps v. Torch Offshore, Inc.* 379 F.3d 207, 216 (5th Cir. 2004) (rejecting Section 11 claim: "The 'total mix' of information normally includes information that is and

has been in the readily available general public domain and facts known or reasonably available to the shareholders"); *In re Merrill Lynch & Co., Inc. Rsch. Reports Sec. Litig.,* 272 F. Supp. 2d 243, 249-50 (S.D.N.Y. 2003) (citing *Klein*, *Wielgos*, and *Seibert*: "Defendants cannot be held liable for failing to disclose . . . information [that] was already public. Sections 11 and 12(a)(2) do not require the disclosure of publicly available information.").

Courts have particularly emphasized this principle, where, as here, the allegedly omitted information is available in public legal and regulatory proceedings. *See, e.g., Sailors v. N. States Power Co.*, 4 F.3d 610, 612 (8th Cir. 1993) (Section 10(b) case: "Much of what the plaintiff argues was hidden from public view is actually part of the regulatory process."); *Haping v. 17 Educ. & Tech. Grp. Inc.*, 2023 WL 8716895, at *11 (S.D.N.Y. July 20, 2023) (regulatory information "Plaintiffs allege should have been disclosed already was in the public domain, [so] there could have been no material nondisclosure under Section 11"); *Garnett v. RLX Tech. Inc.*, 632 F. Supp. 3d 574, 607 (S.D.N.Y. 2022) (dismissing Section 11 claim where "[s]tatements by Chinese government authorities regarding their regulatory aspirations . . . were, by nature, public information"); *Gaer v. Educ. Mgmt. Corp.*, 2011 WL 7277447, at *21 (W.D. Pa. Aug. 30, 2011) (dismissing Section 11 claim because "[n]o legal obligation existed to speculate as to the outcome of" regulatory proceedings and there was no duty "to disclose risks

allegedly associated with publicly available regulatory information"); *Johnson v. Pozen Inc.*, 2009 WL 426235, at *20 (M.D.N.C. Feb. 19, 2009) (Section 10(b) case: "[T]here can be no claim for securities fraud where allegedly concealed facts [about FDA review of a product] have already been disclosed publicly."); *Lau v. Opera Ltd.*, 527 F. Supp. 3d 537, 553 (S.D.N.Y. 2021) ("Where allegedly undisclosed material information is in fact readily accessible in the public domain, . . . a defendant may not be held liable for failing to disclose this information.").

There are good reasons for this principle. As the Third Circuit cautioned 30 years ago: "First," requiring companies to include unnecessary information in SEC filings "would impose an onerous if not insurmountable obstacle on issuers of securities"; "Second, . . . the likely result would be to inundate the investor with what the Supreme Court disparaged as 'an avalanche of trivial information.'" *Trump*, 7 F.3d at 369 n.12, 375 (also emphasizing that "setting the threshold for materiality too low would not serve the remedial purposes of the securities laws").

This case illustrates the issue. The IPO and Exchange Offer Registration Statements were already each more than 700 pages. Investors would not have been helped by Kenvue adding still more pages in order to reprint in-the-weeds details about 8-year-old citizen petitions, 5-to-15-year-old clinical studies, public comments by advocacy groups, and scheduled-then-canceled-then-rescheduled meetings of advisory bodies with no binding authority. The absurdity of Plaintiffs'

theory is underscored when imagining such disclosures for every one of Kenvue's hundreds of products and thousands of ingredients, and for any unresolved regulatory interactions worldwide.

Plaintiffs' Item 105 Allegations Do Not Save Their Claims. The Complaint's last allegation regarding each Registration Statement is that the "specific facts" regarding "the FDA's initiation of regulatory proceedings . . . should have been disclosed" pursuant to Item 105 of Regulation S-K. AC ¶¶ 132-33, 142-43. As a threshold matter, Item 105 does not "create[] an independent cause of action." *Jaroslawicz v. M&T Bank Corp.*, 962 F.3d 701, 711 n.10 (3d Cir. 2020). Plus, this contention suffers from the same flaws addressed above: the omission did not render either Registration Statement misleading, and the publicly available facts were not material and thus did not need to be disclosed under any theory. *See Garnett*, 632 F. Supp. 3d at 612 (dismissing Item 105 claims that were "redundant" of deficient Section 11 and Section 12(a)(2) claims); *Schaffer v. Horizon Pharma PLC*, 2018 WL 481883, at *14 (S.D.N.Y. Jan. 18, 2018) (same); *Gaer*, 2011 WL 7277447, at *23 (no duty "to disclose risks allegedly associated with publicly available regulatory information"); *see also Rudman v. CHC Grp. LTD.*, 217 F. Supp. 3d 718, 730 (S.D.N.Y. 2016) ("[C]ourts typically analyze the sufficiency of Item [105] disclosures with the familiar materiality standard.").

Plaintiffs' invocation of Item 105 additionally falls flat because the risk disclosures in both Registration Statements were compliant. The "Risk Factors" section was 50 pages. *E.g.,* Ex. C at 26-74. In accordance with SEC guidance, it contained various subsections that organized the risks by category, and also contained succinct, bold and italicized summaries of each risk factor followed by text further explaining the risk. *See id.*; *see also* SEC Legal Bulletin No. 7, "Plain English Disclosure," 1999 WL 34984247, *6 (June 7, 1999). The risk disclosures were not generic or boilerplate; throughout, they were specific to Kenvue and its business. Ex. C at 26-74. The disclosures, taken as a whole, satisfied Item 105 by discussing "the most significant factors that make an investment in the registrant or offering speculative or risky." *Jaroslawicz*, 962 F.3d at 705-06; *see also* 17 C.F.R. § 229.105(a) (requiring disclosure of "material" risks).

Notably, the risk disclosures warned investors of the risk of future regulatory action regarding the efficacy of ingredients. The Risk Factor Statement discussed the specific regulatory framework applicable to Kenvue's products and ingredients, and pointed to specific past illustrative examples where risks had materialized, including with Tylenol, Zantac, and sunscreen ingredients. Ex. C at 44-45. That is sufficient to put investors on notice. *See, e.g., In re Proshares Tr. II Sec. Litig.*, 2020 WL 71007, at *9 (S.D.N.Y. Jan. 3, 2020) (dismissing Item 105 allegation where registration statement provided "ample warning" of the type of risk at issue,

and it was "not possible to read the registration statements . . . without understanding" the risk).

That Kenvue did not expressly reference PE or the 8-year-old citizen petition does not create an Item 105 violation that can be bootstrapped to a Section 11 or Section 12(a)(2) claim. "Item 105 does not require disclosure of legal proceedings or regulatory enforcement actions." *In re Walmart Inc. Sec. Litig.*, 2024 WL 1513532, at *7 n.1 (D. Del. Apr. 8, 2024). Nor does it require speculation about how a public proceeding might be resolved. *See Jaroslawicz*, 962 F.3d at 713 ("[R]egistrants need not list speculative facts or unproven allegations."); *Hoey v. Insmed Inc.*, 2018 WL 902266, at *14 (D.N.J. Feb. 15, 2018) ("[A] corporation is not required to disclose a regulatory agency's inconclusive findings, even if they undercut that corporation's position, merely because the drug was described favorably or its strength was touted."). This case illustrates the wisdom of this rule: while Plaintiffs believe certain "adverse facts" made "regulatory action by the FDA . . . probable and imminent" as of Kenvue's May 2023 IPO, AC ¶ 127, they were wrong; more than a year later, the FDA has not taken regulatory action.

C. Kenvue's Opinions About PE Are Not Actionable.

The Third Circuit has instructed that an opinion is actionable only "if it: (i) was not sincerely believed when made; (ii) contains an expressly embedded, untrue factual assertion; or (iii) reasonably implies untrue facts and omits

appropriate qualifying language." *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, 70 F.4th 668, 686 (3d Cir. 2023) (relying on *Omnicare*, 575 U.S. at 183). The Complaint fails to satisfy any of these prongs for the opinions in the Risk Factors Statement and the Tylenol Studies Statement.

The Risk Factors Statement uses classic opinion language: it states that Kenvue "believes its products are reliable, safe and effective," and represented Kenvue's judgment about the risks it believed it faced. *See* AC ¶ 126; *compare Omnicare*, 575 U.S. at 184 (statements of belief and judgments are opinions). The Tylenol Studies Statement described what Kenvue believes certain "[s]tudies . . . have shown," AC ¶ 128, which is an opinion "because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions," *Philip Morris*, 2021 WL 4135059, at *9 (cleaned up).

Plaintiffs do not allege that any Defendant did not sincerely believe these opinion statements. Nor do Plaintiffs allege that the statements contained any untrue factual assertion. Instead, Plaintiffs claim that Kenvue "lacked a reasonable basis [for these opinions], at least with respect to Kenvue's products containing oral PE," and that the statements "failed to disclose facts that seriously undermined the supposed basis for Kenvue's asserted belief." AC ¶¶ 127(i), 137(j). But the test is not whether there exist any facts that might contradict an opinion; it is whether there are "particular (and material) facts going to the basis for the [] opinion . . .

whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Omnicare*, 575 U.S. at 194. As discussed above, no alleged omission made these statements misleading.

Moreover, evaluating these statements through the lens of *Omnicare* further underlines why the Registration Statements were not required to include Plaintiffs' "adverse facts." As *Omnicare* explained, "a reasonable investor does not expect that every fact known to an issuer supports its opinion," and an opinion "is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way." 575 U.S. at 176, 189. The Complaint concedes there was evidence supporting Kenvue's opinions. *See, e.g.,* AC ¶ 12 (noting the "dueling briefs and presentations" at the NDAC meeting). At best, it alleges there was also evidence cutting against Kenvue, and an advisory body sided against Kenvue. That is not sufficient to state a claim. *See, e.g., Turnofsky*, 2023 WL 4527553, at *10.

D. Kenvue Was Not Required To Predict The NDAC's Vote.

Plaintiffs' theory is, at its core, that Defendants should have informed investors that future "regulatory action by the FDA and its NDAC panel was probable and imminent," and there was "a high risk of a determination that oral PE was not effective." AC ¶¶ 127(j)-(k), 129(j), 131(k), 137(k)-(*l*), 139(k), 141(k)-(*l*). But the federal securities laws did not require Kenvue to include in the Registration Statements any prediction that the NDAC would vote to make a non-binding

recommendation to the FDA, let alone a prediction of action by the FDA. Indeed, Plaintiffs' own predictions were wrong and would have misled investors.

First and foremost, there is no allegation that any Defendant *believed* that "regulatory action by the FDA and its NDAC panel was probable and imminent," or that there was "a high risk of a determination that oral PE was not effective." If the Registration Statements had suggested that, they would not have been truthful.

Further, "probable and imminent" and "high risk" are Plaintiffs' judgments. The Complaint provides no explanation for Plaintiffs' opinions other than hindsight based on the NDAC's September 2023 vote. *Cf. Zucker v. Quasha*, 891 F. Supp. 1010, 1017 (D.N.J. 1995) ("[O]missions that create a misleading impression . . . *only in hindsight* [] are not sufficient to constitute the basis of a securities action under section 11."); *Se. Pa. Transp. Auth. v. Orrstown Fin. Servs., Inc.*, 2016 WL 7117455, at *13 (M.D. Pa. Dec. 7, 2016) (same, quoting *Zucker*); *In re TVIX Sec. Litig.*, 25 F. Supp. 3d 444, 450 (S.D.N.Y.), *aff'd sub nom.*, 588 F. App'x 37 (2d Cir. 2014) ("[P]laintiffs are not allowed to plead Section 11 claims with the benefit of 20/20 hindsight" because "claim[s] cannot be based on a 'backward-looking assessment' of the registration statement.").

Even if Plaintiffs' predictions had been correct, the Third Circuit has cautioned against allowing securities claims for "fail[ing] to include a forecast or prediction which failure is [alleged to have been] misleading." *Trump*, 7 F.3d at

371 (discussing the bespeaks caution doctrine). But *Plaintiffs got it wrong despite having the benefit of hindsight* when filing the Complaint in March 2024: "regulatory action *by the FDA*" was not "probable and imminent" as of the May 2023 IPO or the August 2023 Exchange Offer. The FDA still hasn't acted as of the filing of this motion on May 13, 2024.

At bottom, Plaintiffs simply disagree with Kenvue's judgment at the time of the IPO and the Exchange Offer regarding the science on PE's efficacy and the risk and timing of regulatory action regarding the 2015 citizen petition. That does not merit a securities class action. As the Supreme Court has stated, the securities laws are not "an invitation to Monday morning quarterback an issuer's opinions." *Omnicare*, 575 U.S. at 186.

II. The Section 11 And Section 12(a)(2) Claims Should Also Be Limited On Statutory Standing Grounds.

Section 11 and Section 12(a)(2) do not require scienter, i.e., fraudulent intent. 15 U.S.C. § 77k (Section 11); 15 U.S.C. § 77*l*(a)(2) (Section 12(a)(2)). Instead, Congress imposed strict standing requirements and allowed only a "'narrow class of persons'" to bring claims. *See In re FleetBoston Fin. Corp. Sec. Litig.*, 253 F.R.D. 315, 347 (D.N.J. 2008); *see also Obasi Inv. Ltd. v. Tibet Pharm.,*

Inc., 931 F.3d 179, 182 (3d Cir. 2019).[14] These standing requirements provide an independent reason to limit the Complaint's claims by time period and Defendant.

A. There Is No Section 11 Standing After The Exchange Offer.

The Supreme Court recently instructed: "To bring a claim under § 11, the securities held by the plaintiff must be traceable to the *particular* registration statement alleged to be false or misleading." *Slack Techs., LLC v. Pirani*, 598 U.S. 759, 768 (2023) (emphasis added). It emphasized that Section 11's text "uses the definite article to reference the particular registration alleged to be misleading," and therefore to have standing, Plaintiffs must "plead and prove" that they purchased shares traceable to "*the* registration statement" at issue. *Id.* at 767 (emphasis in original). The Complaint does not and cannot plead that any purchases after the Exchange Offer expired on August 18, 2023, are traceable to any particular registration statement. The Section 11 claims therefore should be limited at this stage to the period between the May 4, 2023, IPO and the August 18, 2023, expiration of the Exchange Offer.[15]

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[14] Plaintiffs could have brought Section 10(b) claims, which do not impose these strict standing requirements but instead require scienter. 15 U.S.C. § 78j(b). Plaintiffs strategically chose not to, which is not surprising because it is utterly implausible that any Defendant acted in bad faith.

[15] This limitation matters for several reasons, including: the Section 11 claims for each registration statement involve different sets of shareholders and different Defendants, *compare* AC Count I *with* Count IV; and any damages would be different for each registration statement, *see* 15 U.S.C. § 77k(e) (capping Section

Time-Limited Traceability For IPO Registration Statement Claims. Before the August 2023 Exchange Offer, the only Kenvue shares available to be purchased on the New York Stock Exchange were registered to the IPO Registration Statement. Lead Plaintiff Joseph Ditta alleges that he bought shares on May 10, 2023, six days after the IPO, and thus that his shares are "traceable to the Company's IPO Registration Statement." AC ¶ 20; ECF 18-4 (Ditta certification). Because Ditta acquired shares on the open market at a time when the only shares available for purchase were registered to the IPO Registration Statement, Defendants do not challenge his traceability allegation at this time.

No Tracing After The Exchange Offer Expired On August 18, 2023. The situation is different after the Exchange Offer. Once the Exchange Offer was complete, there were two different sets of registered shares being traded on the New York Stock Exchange: (1) shares registered to the IPO Registration Statement; and (2) shares registered to the Exchange Offer Registration Statement. From that point on, open market purchasers could have bought shares registered to either Registration Statement – and have no way to tell which they received. This precludes traceability after the Exchange Offer expired on August 18, 2023.

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11 damages at "the price at which the security was offered to the public" via the particular registration statement at issue).

The Exchange Offer claims rest on new Plaintiff David Gruthoff, and the allegations about him illustrate the problem. The Complaint alleges that Gruthoff "acquired shares of Kenvue common stock pursuant and/or traceable to the Exchange Offer Registration Statement." AC ¶ 21. But this conclusory recitation of the traceability element is not supported by the factual allegations about Gruthoff's acquisition of Kenvue stock. Gruthoff's certification filed with the Complaint attests that he "received" Kenvue stock on August 25, 2023, "following an Exchange Offer held by Johnson & Johnson." ECF No. 38-1 (emphasis added). That was seven days *after* the Exchange Offer expired on August 18, 2023. By that time, shares registered to the Exchange Offer Registration Statement were intermingled with shares registered to the IPO Registration Statement in the market. "For all anyone could tell, [Gruthoff] may have purchased [] shares unconnected to the [Exchange Offer] registration statement." *Slack*, 598 U.S. at 765; *see also In re Century Aluminum Co. Sec. Litig.*, 729 F.3d 1104, 1106-08 (9th Cir. 2013) (dismissing Section 11 claims based on similar pursuant and/or traceable to allegation "because it is devoid of factual content"; where multiple offerings are at issue, "a greater level of factual specificity will be needed" because the "obvious alternative explanation" is that the plaintiffs' shares "could instead have come from the pool of previously issued shares"); *In re Ariad Pharms., Inc. Sec. Litig.*, 842 F.3d 744, 756 (1st Cir. 2016) ("[G]eneral allegation that a

plaintiff's shares are traceable to the offering in question is nothing more than a 'formulaic recitation' of that element."); *De Vito v. Liquid Holdings Grp., Inc.*, 2018 WL 6891832, at *17 (D.N.J. Dec. 31, 2018) ("[B]road, boilerplate allegation of traceability . . . assuming it was ever sufficient, is no longer sufficient after *Twombly* and *Iqbal*.").

B. There Is No Section 12(a)(2) Standing For Claims Against The Individual Defendants, J&J, Or The Underwriter Defendants.

Section 12(a)(2) imposes liability only on a person who "offers or sells a security," and only grants a cause of action to "the person purchasing such security from him." 15 U.S.C. § 77*l*(a)(2). Courts have interpreted this language to circumscribe statutory standing to "statutory sellers" who "pass[] title to the buyer for value (a direct seller) or [] who successfully solicit[] the purchase . . . (a solicitor seller)." *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 716 (3d Cir. 1996); *see also, e.g., Lozada v. TaskUs, Inc.*, 2024 WL 68571, at *15 (S.D.N.Y. 2024). The Complaint fails to plead either direct purchases or solicitation for any Individual Defendant, J&J, or any Underwriter Defendant.

The Complaint Does Not Allege Any Direct Purchases. The Complaint's only allegation about Ditta's purchases is that they were "pursuant or traceable to the Company's IPO Registration Statement." AC ¶ 20. The only allegation about Gruthoff's purchases is that they were "pursuant and/or traceable to the Exchange Offer Registration Statement." *Id.* ¶ 21. The Complaint does not allege that either

Plaintiff bought from any Defendant, and therefore there are no direct seller claims. *See Ballay v. Legg Mason Wood Walker, Inc.*, 925 F.2d 682, 684 (3d Cir. 1991) (Section 12(a)(2) does not "protect buyers in the aftermarket").

The Complaint Does Not Adequately Allege Solicitation. The Complaint vaguely alleges that "Defendants" "actively solicited purchasers of stock for the [IPO or Exchange Offer] by, among other things, preparing, disseminating, and presenting to individual investors and otherwise eliciting investor participation in the [IPO or Exchange Offer]." AC ¶¶ 165 (Count II, IPO), 193 (Count V, Exchange Offer). It also alleges that the "Underwriter Defendants solicited and sold shares of Kenvue common stock to Plaintiffs and other members of the Class in the IPO." *Id.* ¶ 62(f). These conclusory allegations are insufficient.

The Third Circuit has explained that Section 12(a)(2) requires "direct and active participation in the solicitation of the immediate sale." *Craftmatic*, 890 F.2d at 636. "To count as 'solicitation,' the seller must, at a minimum, directly communicate with the buyer." *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 871 (5th Cir. 2003). There are no facts pleaded about what *any* Defendant did to directly or actively solicit Ditta's or Gruthoff's purchases, or that either Plaintiff had any communications with any Defendant. Rather, Plaintiffs' Section 12(a)(2) claims are premised on the contention that merely participating in the IPO or the Exchange offer suffices to become a solicitor seller. *See* AC ¶¶ 165, 193. But

courts have long rejected that approach to pleading Section 12(a)(2) claims. *See, e.g., Citiline Holdings, Inc. v. iStar Fin. Inc.*, 701 F. Supp. 2d 506, 512 (S.D.N.Y. 2010) ("Every Court of Appeals to have considered the issue . . . has held that an individual's signing a registration statement does not itself suffice as solicitation under Section 12(a)(2)."); *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1216 (1st Cir. 1996) ("[N]either involvement in preparation of a registration statement or prospectus nor participation in 'activities' relating to the sale of securities, standing alone, demonstrates the kind of relationship between defendant and plaintiff that could establish statutory seller status."); *Allison v. Oak St. Health, Inc.*, 2023 WL 1928119, at *14 (N.D. Ill. Feb. 10, 2023) (dismissing Section 12(a)(2) claims that did not allege "details regarding the role played by the defendants in the solicitation of the securities at issue") (cleaned up).

For these reasons, the Section 12(a)(2) claims against every Individual Defendant, J&J, and every Underwriter Defendant should be dismissed. The Section 12(a)(2) claims should be limited to Kenvue. *See* AC ¶¶ 165 (Count II) & 193 (Count V) (alleging "Kenvue was a statutory seller under SEC Rule 159A").

III. The Complaint Fails To Plead Section 15 Control Person Liability.

The Section 15 claims fail because Plaintiffs have not pled any predicate Section 11 or Section 12(a)(2) claims. *See Turnofsky*, 2023 WL 4527553, at *12.

The Section 15 claims should also be dismissed because the Complaint's allegations of the other elements – control and culpable participation – are conclusory. *See Carmack*, 258 F. Supp. 3d at 466. Plaintiffs allege the Individual Defendants were controllers because of their "positions as senior officers or directors of Kenvue," and that J&J was a controller because it was Kenvue's "controlling shareholder." AC ¶¶ 172, 200. Plaintiffs allege that the third element of a Section 15 claim is satisfied because these Defendants were "culpable participants in the [alleged predicate] violations." *Id.* ¶¶ 177, 205.

These bare assertions about an undifferentiated group of Defendants do not state a claim. *See In re Weight Watchers Int'l Inc. Sec. Litig.*, 504 F. Supp.3d 224, 263 (S.D.N.Y. 2020) ("Boilerplate allegations of control based on one's status as an officer or director are generally insufficient to establish control.") (cleaned up); *Bondholder Comm. v. Sauk Valley Student Housing, LLC*, 2018 WL 3405263, at *3 (D.N.J. July 11, 2018) ("Courts in this district have held that group pleading does not satisfy the plausibility requirement.").

CONCLUSION

For the above reasons, the Complaint should be dismissed with prejudice.

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Respectfully submitted,

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